DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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March 21, 2002

Ralph Snyderman, M.D.
President
Duke University Health System, Inc.
DUMC Box 3701
Durham, North Carolina 27710

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)M-1106

Research Publication: Ventilation with Lower Tidal Volumes as Compare with Traditional Tidal Volumes for Acute Lung Injury and the Acute Respiratory Distress Syndrome (N Eng J Med 2000;342:1301-8)
HHS Project Number: N01-HR46056
IRB Project Number: 186-96-2
Principal Investigator: William Fulkerson, M.D.

Dear Dr. Snyderman:

The Office for Human Research Protections (OHRP) has reviewed Duke University Health System's (DUHS's) March 4, 2002 letter, as well as all previous correspondence regarding the above-referenced research.

Based upon its review, OHRP makes the following determinations regarding DUHS's oversight of the above-referenced research:

(1) In its February 1, 2002 letter, OHRP found that the DUHS IRB failed to satisfy requirements under Department of Health and Human Services regulations 45 CFR 46.117(a) when it approved a telephone consent procedure under which the investigator did not obtain a signed informed consent document from the subject's legally authorized representative.

OHRP finds that DUHS has implemented appropriate corrective action plans to ensure that

informed consent is documented by use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, and that any waiver by the IRB for the requirement for the investigator to obtain a signed informed consent document is in accordance with the requirements under 45 CFR 46.117(c).

(2) HHS regulations at 45 CFR 46.111(b) stipulate that in order to approve research, the IRB shall determine that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of the subjects. OHRP finds that DUHS has implemented appropriate corrective actions to improve IRB procedures to ensure adequate review and documentation of safeguards that might be necessary for the protection of vulnerable subjects.

(3) OHRP finds that DUHS has adequately addressed the additional concerns found in OHRP's February 1, 2002 letter.

As a result of the above determinations, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the commitment of DUHS to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Leslie K. Ball, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. John Falletta, Chair, IRB-01, DUHS
Ms. Charlotte Coley, IRB Administrator, DUHS
Dr. William Fulkerson, Pulmonary/Critical Care Medicine, DUHS
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey Cohen, OHRP
Ms. Janice Walden, OHRP
Mr. Barry Bowman, OHRP
Commissioner, FDA

Dr. David Lepay, FDA

Dr. James McCormack, FDA